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EXAMINER	
WELTER, RACHAEL E	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,157	BREITENBACH, ARMIN	
	Examiner	Art Unit	
	RACHAEL E. WELTER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-19* is/are pending in the application.

4a) Of the above claim(s) *20-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-19* is/are rejected.

7)☒ Claim(s) *12 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/6/04 & 11/19/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Applicant's Election

Applicant's election with traverse of Group I (claims 12-16) in the reply filed 5/27/08 is acknowledged. A restriction was made to restrict the pending claims 12- 28 in to the following groups:

I. Claims 12-16

II. Claims 17-19

III. Claims 20-25

IV. Claims 26-28

According to applicant, all the claims of Groups I-III share not only the feature "a matrix for transdermal administering of rotigotine" but all the limitations of claim 12 or alternatively claim 13.

The examiner does note that a mistake was made in the previous restriction requirement mailed 4/24/08. The examiner asserted that the common technical feature was taught by Lauterbach et al (US 2003/0027793). However, the examiner should have also combined Lauterbach et al with Farinas et al (US Patent No. 5,906,830). The combination of these references meets the limitations of the independent claims: claim 12 or alternatively claim 13.

Lauterbach et al teach a silicone based transdermal therapeutic system containing rotigotine as an active ingredient (abstract). Farinas et al teach methods for manufacturing transdermal drug delivery systems containing supersaturated drug reservoirs that are free of dispersants, solvents, and crystallization inhibitors (abstract).

Farinas et al teach that the supersaturated drug reservoirs obtain higher drug fluxes (abstract). Lauterbach et al do not teach that the matrix polymer is supersaturated with a rotigotine base. Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to make delivery systems containing supersaturated drug reservoirs. One would have been motivated to make such a system because higher drug fluxes are obtained.

The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any). Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," should be considered with respect to novelty and inventive step.

Thus, the inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Furthermore, the examiner will allow claims in Group II (claims 17-19) to be examined with the elected claims in Group I (claims 12-16). The examiner has reconsidered the following groups because the transdermal system is made up of a matrix administering rotigotine. However, claims in Group III and IV will maintain their nonelected status because they not only lack unity but they are drawn to patentably distinct methods of using and making respectively.

Thus, the restriction requirement is deemed proper and is therefore made FINAL.

Note: ***Claims 12-28 are pending***
Claims 12-19 are elected.

Acknowledgments

The Examiner acknowledges receipt of the preliminary amendment filed 5/27/08 wherein the claims were amended to correct errors in dependency and spelling. The examiner further acknowledges the replacement of the word "comprising" for "containing" in claim 12.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on December 6, 2004 and November 19, 2007 were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. A signed copy of forms 1449 are enclosed herewith.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. No English translation of the Certified Copy of the Foreign Priority Application has been received.

Claim Objections

Claims 12 and 19 are objected to because of the following informalities. Several typos are present in the instant claims. In claim 12, it seems that applicant means the

term "dispersants" instead of "dispergents." In claim 13, the charge of ritigotine should be given in mg/cm^2 not mg/cm^3. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauterback et al (US Publication No. 2003/0027793) in view of Farinas et al (US Patent No. 5,906,830) and Taylor et al (WO 92/014442).

Claims 12-19 are drawn a matrix for transdermal administering of rotigotine comprising a matrix polymer supersaturated with rotigotine base, wherein a portion of the rotigotine is dispersed in the matrix polymer as amorphous particles with a maximum mean diameter of 30 um. The matrix is free of solvents, crystallization

inhibitors, and dispersants and could optionally include one or more antioxidants. The matrix polymer is an amine-resistant silicone or a mixture of amine-resistant silicones and is a self-adhesive. The contents of the matrix consist of 60-95 wt.% amine-resistant silicone, 5-40 wt.% amorphous rotigotine base, and 0-2 wt.% antioxidant. Furthermore, the system for transdermal administering of rotigotine comprises a backing that is impermeable to rotigotine. Finally, the rotigotine charge is between 0.3 - 6 mg/cm^2.

Lauterback et al teach a silicone-based transdermal therapeutic system that contains 0.1-3.15 mg/cm^2 of rotigotine as an active ingredient (abstract). According to Lauterback et al, the silicone-based system must contain at least one amine resistant silicone compound as the main component (paragraph 0017). Lauterback et al teach that usually the silicone compound will be a pressure sensitive adhesive and will form a matrix in which the other components of the system are embedded (paragraph 0017). Furthermore, Lauterback et al teach the amounts of composition components in a table found in paragraph 0041. Rotigotine base is 9 wt.%, the amine resistant silicone compound is 89 wt.%. Moreover, Lauterback et al teach the addition of antioxidants such as ascorbyl palmitate, DL-alpha tocopherol, and sodium metabisulfate (table in paragraph 0041). These antioxidants are present at 0.02 wt.%, 0.05 wt.%, and 0.0006 wt.% respectively. Lauterback et al do not teach a transdermal system comprising a matrix polymer supersaturated with rotigotine base. In addition, Lauterback do not teach a matrix free of solvents, crystallization inhibitors, and dispersants. The use of a solubilizer is taught in paragraph 0022. Finally, Lauterback et al do not teach a backing layer for the transdermal system.

Farinas et al teach methods for manufacturing transdermal drug delivery systems containing supersaturated drug reservoirs (abstract). According to Farinas et al, a backing layer serves as the upper surface of the device and is substantially impermeable to the drug (column 4, lines 6-9). In addition, Farinas et al teach a polymer-drug admixture that results in a system with two liquid phases, one that contains polymer and one that contains drug (column 6, lines 36-41). Farinas et al teach that the drug phase when quenched rapidly becomes an amorphous, glass phase at ambient conditions (column 6, lines 42-44). Furthermore, Farinas et al teach that if a solvent is used, it is removed during or before heat treatment (column 8, lines 7-9). Farinas et al do not teach the addition of any crystallization inhibitors or dispersants and list that they are optional (column 8, lines 14-21). Finally, Farinas et al teach that the drug formulation may also include standard carriers or vehicles useful for facilitating drug delivery, like antioxidants (column 8, lines 14-16).

Taylor et al teach a composition for transdermal administration of a biologically active agent wherein the active agent is present in an amount above its solubility limit and wherein the active agent is present in fine particles throughout said carrier to facilitate transdermal transfer of the composition (abstract). According to Taylor et al, at least 60% of the particles are sized at less than 20 microns (pg. 5, lines 3-4). Taylor et al teach that the rate of transdermal delivery of the active ingredient is increased and controlled by having at least a substantial proportion of the active compounds present in the form of fine particles (pg. 4, lines 9-15).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to make a transdermal system that contains a backing layer and supersaturated drug reservoirs free of solvents, crystallization inhibitors, and dispersants. One would have been motivated to use a backing layer to protect the upper surface of the device and prevent the drug from leaking out. Furthermore, one would have been motivated to use a matrix free of solvents, crystallization inhibitors, and dispersants to reduce costs, time and effort.

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to make a transdermal system containing supersaturated drug reservoirs. One would have been motivated to make such a system because higher drug fluxes are obtained. In addition, one would have been motivated to make a system with an active ingredient present in the carrier in the form of fine particles to increase and control drug release.

Conclusion

Claims 12-19 are rejected. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW
/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611